UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,831	03/26/2004	Thomas R. Kozel	031673-3000	7955

22204 7590 04/03/2006

NIXON PEABODY, LLP
401 9TH STREET, NW
SUITE 900
WASHINGTON, DC 20004-2128

EXAMINER	
SWARTZ, RODNEY P	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 04/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/809,831	KOZEL ET AL.	
	Examiner	Art Unit	
	Rodney P. Swartz, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 January 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-21 and 33-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-21,33-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' Response to Office Action, received 3 January 2006, is acknowledged. Claims 1, 9-14, and 22-32 have been canceled. Claims 15, 20, 21, and 34 have been amended. New claims 37-61 have been added.

2. Claims 15-21 and 33-61 are pending and under consideration.

Rejections Moot/Withdrawn

3. The rejection of claim 9 under 35 U.S.C. 112, second paragraph, as being indefinite, is moot in light of the cancelation of the claim.

4. The rejection of claim 22 under 35 U.S.C. 112, second paragraph, as being indefinite, is moot in light of the cancelation of the claim.

5. The rejection of claim 22 is rejected under 35 U.S.C. 112, second paragraph, for lack of antecedent basis, is moot in light of the cancelation of the claim.

6. The rejection of claim 9 under 35 U.S.C. 102(b) as being anticipated by Froman et al (*Journal of Reproduction and Fertility*, 88(2):405-410, 1990), is moot in light of the cancelation of the claim.

7. The rejection of claims 15-21 under 35 U.S.C. 112, second paragraph, as being indefinite, is withdrawn in light of the amendment of claim 15.

8. The rejection of claim 21 under 35 U.S.C. 112, second paragraph, as being indefinite, is withdrawn in light of the amendment of the claim.

9. The rejection of claims 15, 16 and 18 under 35 U.S.C. 102(b) as being anticipated by Froman et al (*Journal of Reproduction and Fertility*, 88(2):405-410, 1990), is withdrawn in light of the amendments to the claims.

Rejections Maintained

10. The rejection of claims 33-36 under 35 U.S.C. 112, first paragraph, scope of enablement for detection or staging of anthrax infection, is maintained.

Applicants argue that Example 7 in the instant specification does not teach that soluble PGA exists in normal adults who have high levels of anti-γDPGA antibodies. Schneerson et al does not teach that soluble PGA exists in blood or other tissues of *Bacillus*-infected individuals. Therefore, one of ordinary skill in the art would not believe that individuals who have high levels of anti-γDPGA necessarily have detectable soluble PGA in their blood or other tissues.

The examiner has considered applicants' argument, but does not find it persuasive. Firstly, the claims are drawn to determining levels of soluble PGA, not soluble γDPGA, in a biological sample. Both the instant specification and Schneerson et al teach that *B. anthracis* synthesizes only γDPGA, but other *Bacillus* species also produce PGA of both forms. Neither the instant specification nor Schneerson et al indicate that there is something totally unique about the species of *B. anthracis* which precludes any other species of *Bacillus* from providing soluble PBA in blood or other tissues of *Bacillus*-infected individuals. Therefore, how does one distinguish between infection with *B. anthracis* and any other *Bacillus* species when one detects any form of PGA, as the claims are directed, versus only γDPGA.

New Rejections Necessitated by Amendment

Claim Rejections - 35 USC § 112

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Newly amended claims 15-21 and new claims 36-61 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for detection of level of PGA in samples using anti-PGA, does not reasonably provide enablement for detection or staging of anthrax infection in light of applicants' comments, page 36, Example 7. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are drawn to a method for detecting or staging anthrax infection in a vertebrate of interest comprising contacting a biological sample prepared from said vertebrate with an anti-PGA antibody to detect a level of soluble PGA or γDPGA in said biological sample, wherein the level of soluble PGA or γDPGA in said biological sample is indicative of anthrax infection, or state thereof, in said vertebrate.

The specification teaches in Example 7, pages 36-37, that "PGA is produced by several *Bacillus* species that are likely to be encountered in the environment. Such exposure to either saprophytic *Bacillus* species or to *Bacillus anthracis* itself would lead to production of PGA antibodies. This is a common phenomenon in which exposure to naturally-occurring antigens leads to eventual production of high levels of antibodies to many capsular polysaccharides. The results showed that normal adults produce anti-γdPGA IgG and IgM (Figure 10). The titers are normally distributed; some individuals have quite high levels of antibody." In addition, Schneerson et al (*PNAS*, 100(15):8945-8950 teach that "Other bacilli produce poly(γ-glutamic acid)(γPGA), but only *B. anthracis* synthesizes it entirely in the D conformation" (page 8945, col 1, bottom).

The specification does not teach how to distinguish between levels of soluble PGA or γDPGA which are the result of "exposure to saprophytic *Bacillus* species" from exposure to

Bacillus anthracis. Neither the instant specification nor Schneerson et al indicate that there is something totally unique about the species of *B. anthracis* which precludes any other species of *Bacillus* from providing soluble PBA in blood or other tissues of *Bacillus*-infected individuals. Thus, the scope of the claims constitute merely an invitation to experiment without a reasonable expectation of success.

Conclusion

13. No claims are allowed.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (571)272-0864.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER
Art Unit 1645

March 29, 2006